



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,033	03/26/2004	Scott L. Weinrich	011/007C	9946

22869 7590 04/26/2005

GERON CORPORATION
230 CONSTITUTION DRIVE
MENLO PARK, CA 94025

EXAMINER

SAIDHA, TEKCHAND

ART UNIT PAPER NUMBER

1652

DATE MAILED: 04/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/811,033

Applicant(s)

WEINRICH ET AL.

Examiner

Tekchand Saidha

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2004.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-25 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to 'Notice to File Corrected Application Papers', filed August 2, 2004, is acknowledged.
2. Claims 1-25 are pending and under consideration in this examination.
3. ***Continuation of prior application***

When a non-provisional application claims the benefit under 35 USC 120 of a prior application 10/330,872....., the first sentence of the specification should read, e.g., "This application is a continuation of U.S. Application No. 10/330,872, filed December 24, 2002, now US Patent No. 6,787,133, which is continuation.....

The current status of the application, as indicated above, needs to be amended.

New Matter Rejection

4. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-25 are drawn to a method for producing a compound that regulates telomerase activity. There is no basis in the specification as filed to a 'method of producing a compound.. (claims 1-25)' and method step [for example, claim 1(e) or claim 2(b)], for '....producing the compound if it is identified....'.

5. ***Written Description***

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes a method of purifying human telomerase protein (200-2000 kDa) from adenovirus-transformed kidney cell line (293 cells), 90-fold and still retaining 29% of the activity (or losing 71% activity) using an oligo-5-affinity column (see Table 4) which can be used to for developing methods to regulate telomerase activity (see Specification, page 3, lines 3-4), thus providing an intent to future development for a method to identify and produce regulators of telomerase without actually describing a single representative species (or method) or having used or disclosed a regulator (inhibitor or activator) of telomerase, let alone produce the same (claims 1-25). There is no disclosure in the method of the size/structure of the mammalian telomerase used or the size/structure of the oligonucleotide used (see for example claims 1-2), other than the range of the molecular weights (200-2000 kDa) of telomerase enzyme containing the RNA component. With such a vague and varying description of a genus it is impossible to establish a relationship among species and claimed genus which uses a entire range of telomerases. Telomerase proteins of various molecular sizes are known. The human telomerase protein is also known to made of distinct subunits, for example, 140 kDa, 105 kDa, 48 kDa and 43 kDa. Telomerases are ribonucleoprotein comprising a protein and an RNA component. There is no description in the specification for (1) a method of identifying a regulator (activator or inhibitor) of telomerase activity, as well as a (2) method for producing a compound that regulates telomerase activity. Neither a regulator compound has been identified nor a method of producing it has been described in the instant specification. The specification discloses not a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Claims 3-25 have been included in this rejection because they incorporate the broad genus of claims 1 & 2, which remains undescribed.

6. ***Claim Rejections - 35 USC § 112*** (second paragraph)

Claims 20-21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20-21 recites the limitation "telomerase core enzyme" in claim 1 or claim 2. There is insufficient antecedent basis for this limitation in the claim. Claims 20-21 are rejected for lack of antecedent basis.

7. ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or

Art Unit: 1652

patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1-25 are rejected under the judicially created doctrine of double patenting over claims 18-20 of U. S. Patent No. **6,517,834** or over claims 1-25 of U. S. Patent No. **6,787,133**, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patents and the application are claiming common subject matter, as follows: A method for assessing a regulator of telomerase, which uses the obvious variation of method steps of measuring the telomerase activity in the presence of a regulator, where the regulator is a telomerase inhibitor or activator, and having identified the regulator producing the same.

8. No claim is allowed.

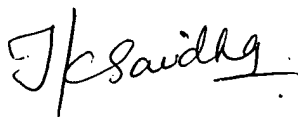
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571)

Art Unit: 1652

272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Tekchand Saidha
Primary Examiner, Art Unit 1652
Recombinant Enzymes, 02A65 Remsen Bld.
400 Dulany Street, Alexandria, VA 22314
Telephone : (571) 272-0940

April 18, 2005